REMARKS

MPEP §803 describes when restriction in an application is proper.

> There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (see MPEP §802.01, §806.04, §808.01) or distinct as claimed (see MPEP §806.05 - §806.05(i)); and (B) There must be a serious burden on the examiner if restriction is required (see MPEP §803.02, §806.04(a) - §806.04(i), §808.01(a), and §808.02).

Both criteria must be met and the applicants submit that the examiner has failed to adequately address the issue of "serious burden" set out in part (B).

In each embodiment of the invention, the endpoint of the claimed method is provided using a common active agent. For example, the endpoint in claim 55 is inactivation of heparin (or low molecular weight heparin) is inactivated, in claim 57 the endpoint is amelioration of an effect of heparin (or low molecular weight heparin), and in claim 58, the endpoint is treating or preventing undue or excessive bleeding. Presumably, the differences between the recited endpoints gave rise to the examiner's assertion that the subject matter of the claims are classified differently. Accordingly, by focusing on the end result rather than the common active agent, the examiner was only then able to assert different classifications and provide any basis for asserting a "serious burden."

However, as stated above, attaining each embodiment requires use of the same active agent, *i.e.,* a purified protamine which is bioactive, has a molecular weight of between about 400 and about 2500 Daltons, and has reduced immunosuppressiveness or toxicity compared to native proteins. Thus, rather than conducting individual searches for each treatment endpoint (which arguably could be effected by any of a number of possible active agents), the examiner could instead carry out a single search for the "protamine" active agent.[1] Having

[1] According to http://www.uspto.gov/go/classification/uspc530/defs530.htm#C530S350000, protamines are categorized in class 536 (Organic compounds), subclass 358 (Nucleoproteins, i.e., chromatin, chromosomal proteins, histones, protamines, salmine, etc.).

first identified any art potentially relevant to a "protamine" agent *per se*, the search could then easily be narrowed by including additional search terms such as "heparin" or "bleeding" to determine if such uses were previously known or suggested.

The applicants therefore submit that with carefully selected terms, the invention in its entirety could be searched a single search which would not be a serious burden on the examiner. Accordingly, the applicants request that the restriction requirement bed withdrawn and all claims examined in this application.

Dated: July 18, 2005

Respectfully submitted,

By _____
Joseph A. Williams, Jr.
Registration No.: 38,659
MARSHALL, GERSTEIN & BORUN LLP
233 S. Wacker Drive, Suite 6300
Sears Tower
Chicago, Illinois 60606-6357
(312) 474-6300
Attorney for Applicant